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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/849,036

05/20/2004

Raimund Schaller

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7055 7590 05/29/2008
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EXAMINER

MAHYERA, TRISTAN J

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

05/29/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/849,036	Applicant(s) SCHALLER, RAIMUND	
	Examiner TRISTAN J. MAHYERA	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-11,14,15,18-20 and 53-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-11,14,15,18-20 and 53-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/21/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-5, 9-11, 14, 15, 18-20 and 53-55 under 35 U.S.C. 112, second paragraph, is hereby **withdrawn** in light of applicant's amendments.

Claim Rejections - 35 USC § 102

The statutes under this section can be found in a previous Office Action.

The rejection of claims 1-5, 9-11, 19, 20, 53 and 54 under 35 U.S.C. 102(b) as being anticipated by DRESDNER is hereby **withdrawn** in light of applicant's arguments and clarification.

Claim Rejections - 35 USC § 103

The statute under this section can be found in a previous Office Action.

The rejection of Claims 1-5, 9-11, 14, 15, 18-20 and 53-55 is hereby **withdrawn** in light of applicant's arguments and clarification.

Claims 1-5, 9-11, 18-20, 53 and 54 are **newly** rejected under 35 U.S.C. 103(a) as being unpatentable over SCHALLER (US 6,254,947, see PTO-1449) in view of TERRY (US 2005/0064176, see PTO-892, dated 11/21/2007).

SCHALLER teaches recesses and raised areas in the anti-friction layer of a multi-layer medical glove article. See Fig. 1. An elastomeric base layer (i.e. carrier layer) with an internal and external surface and an anti-friction layer (i.e. slip layer) comprised of a polymeric material with raised areas and recesses that extend through the anti-friction layer to the base layer. See e.g. col. 9 lines 26-34, col 11 lines 4-7 and lines 25-33; instant claims 1 and 53. The base layer contains synthetic latex (see e.g. col. 5 lines 10-13) or natural latex (see e.g. col. 5 line 9); instant claim 54. The reference is silent on the percent range of recesses (20-95%) that extend through to the base layer, however, Fig. 1 shows the majority of recesses extend to the base layer, thus it is the opinion of the Examiner that the reference reads on the instant range. The thickness of the anti-friction layer is between 2 and 80 microns (see col. 9 lines 31-34; instant claims 19 and 20). SCHALLER does not teach the use of particles within the article.

TERRY teaches the use of antimicrobial particles in a coating that is applied to a substrate or device. The substrate is a medical glove or condom made of latex wherein the particles can be applied into one layer (base layer) while keeping a second layer particle free. See e.g. claims 1, 2 and 14. The average particle size is up to about 100 microns making the particle at least 80% of the thickness of the anti-friction layer. See e.g. claim 5; instant claims 2-5. Both water soluble particles (e.g. copper sulfate) and water insoluble particles (e.g. silver zeolite) are taught. See e.g. p[0023]; instant claims 10-11. TERRY contemplates the use of non-silver and non-copper containing particles. See e.g. p[0023] last sentence.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make an article such as a medical glove or condom comprising an anti-friction layer, an elastomeric base layer and pharmaceutically active particles present in or between the layers, as taught by SCHALLER in view of TERRY. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single article because of the beneficial effects of incorporating an active pharmaceutical into a glove or condom to prevent the spread of microbes, as taught by TERRY. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Claims 1, 14, 15 and 55 are **newly** rejected under 35 U.S.C. 103(a) as being unpatentable over SCHALLER (US 6,254,947, see PTO-1449) in view of TERRY (US 2005/0064176, see PTO-892) and in further view of HAMANN (US 2004/0091504, see PTO-892, dated 11/21/2007).

SCHALLER teaches recesses and raised areas in the anti-friction layer of a multi-layer medical glove, as taught above. SCHALLER does not teach the use of plant extracts or vitamins in the article.

TERRY teaches the use of particles in and on a medical glove or condom, as taught above.

HAMANN teaches a multi-layer prophylactic article or glove wherein a plant extract is incorporated into an elastomer layer of the article or glove. See page 6

Art Unit: 1615

paragraph [0038] and claim 37. The extract is incorporated into the inner layer, between the layers, in contact with the skin on the wearer or at all of the mentioned areas. See Figures 3-9. The extract is taught to contain therapeutic components such as anti-microbial or anti-aging. See claim 3. The plant extract consists of vitamins such as E, A, C and Nopal. See claims 30, 33, 34 and 35; instant claims 4, 15 and 55.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a medical glove or condom comprising plant extracts or vitamins, as taught by SCHALLER in view of TERRY and in further view of HAMANN. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single glove or condom wherein particles of plant extracts and vitamins are incorporated into the article because of the beneficial effect anti-microbials and vitamins have on anti-aging (such as moisturizing) and microbe control, as taught by HAMANN. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

Art Unit: 1615

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 9-11, 18 and 53 are **newly** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 16-18 and 30 of U.S. Application No. 2008/0040834 (see PTO-1449). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is directed to a prophylactic article or medical glove comprising an elastomeric base layer, an anti-friction layer and particles that contain an active or dye.

Art Unit: 1615

The '834 application is directed to a prophylactic article or medical glove, of at least one elastomeric base layer and in some areas an anti-friction layer whereby microcapsules are contained in the anti-friction layer. The claims differ in the size of the particles, with the '834 application claiming 90% of the particles are below 10 microns and the instant claiming the particles have an upper diameter of 500 microns and a lower limit of 10 microns, however, the size of particles is a variable parameter within the art and it is within the skill of a person in the art to increase or decrease the particle size. Furthermore, the '834 application has up to 10% of the particles within the size range of the instant application. Therefore, it would have been obvious to a person of ordinary skill in the art to vary the particle size within the prophylactic article to achieve the particle size of the instant application. Absent any evidence to the contrary, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Friday 9am-7pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373.

Art Unit: 1615

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615